# LEGISLATIVE SERVICES AGENCY
## OFFICE OF FISCAL AND MANAGEMENT ANALYSIS

301 State House
(317) 232-9855

## FISCAL IMPACT STATEMENT

**LS 6890** **DATE PREPARED:** Dec 22, 2000
**BILL NUMBER:** SB 328 **BILL AMENDED:**

**SUBJECT:** Newborn Medical Screening.

**FISCAL ANALYST:** Kathy Norris
**PHONE NUMBER:** 234-1360

**FUNDS AFFECTED:** X **GENERAL** **IMPACT:** State & Local
X **DEDICATED**
X **FEDERAL**

**Summary of Legislation:** This bill expands the Newborn Screening Program, which requires infants to be examined for certain disorders, to include inborn metabolic disorders designated by the State Board of Health that result in significant illness or death. (Current law allows the Department to designate inborn errors of metabolism that result in mental retardation.)

**Effective Date:** July 1, 2001.

**Explanation of State Expenditures:** *Summary:* This bill will allow the expansion of the inborn metabolic disorders testing that the Department of Health may require every infant to undergo at the earliest feasible time. The estimated General Fund impact of an expansion in the number of metabolic disorders screened is $303,500. This includes additional costs to the Medicaid program and the state employee health plans. This dollar amount also does not include costs associated with the ongoing medical treatment and nutritional therapy needed by affected individuals identified by the screening program.

*Background:* Current state law requires screening for: phenylketonuria, hypothyroidism, hemoglobinopathies, galactosemia, maple syrup urine disease, homocystinuria, and allows screening for other inborn errors of metabolism that result in mental retardation and that are designated by the State Department of Health. This bill permits the Department to consider requiring tests for other inborn errors of metabolism that do not cause mental retardation but may result in serious illness or death.

The Department has recently added two additional conditions to the required newborn screening; biotindinase deficiency and virilizing adrenal hyperplasia. Some of the other additional disorders (permitted to be screened by the bill) with early diagnosis and dietary adjustments can have significantly better outcomes; others can be detected and diagnosed but do not respond consistently to treatment.[1]

The availability of new laboratory testing equipment is the impetus behind the expansion of the newborn

screening program. Tandem mass spectrometry is a relatively new technology that permits rapid, sensitive, and accurate measurement of many different kinds of metabolites requiring minimal sample preparation. The computerized system has the capability to handle the large numbers of samples that are processed in newborn screening programs. Tandem mass spectrometry cannot replace all current tests used to screen for all of the currently required conditions. However, it is a more accurate and sensitive test for certain required screens (phenylketonuria, maple syrup urine disease, and homocystinuria) and permits the screening program to be expanded to include a number of disorders (approximately 30) that are not currently covered under the provisions of the statute. Some of these disorders are relatively common, difficult to detect before the onset of symptoms, and whose outcome is substantially improved by early treatment.

The Department of Health currently screens about 84,000 infants annually, or 99.6% of all births in the state, for eight conditions. The current laboratory charge for the screening test is about $22.50. The laboratory charge is based on the cost necessary to screen all infants. Even if a repeat screen is necessary, there is no additional charge for the laboratory. This is significant since if the laboratory samples are collected too early, the screens must be repeated. Repeat screens are performed on approximately 50% of the infants. In addition the Department adds on a $7 fee for the administrative expenses associated with the Newborn Screening Program. Hospitals may have an additional associated phlebotomy charge for the collection of the specimen.

Allowing the expansion of the Newborn Screening Program would not necessarily mean that the Department would automatically start using tandem mass spectrometry. However, should the opportunity to convert selected existing testing protocols to the more accurate test arise, the Department could take full advantage of the expanded capacity of the tandem mass spectrometry. Indiana University currently is the contracted laboratory for the state newborn screening exams. IU does not currently have tandem mass spectrometry equipment capable of performing the screens for all newborns in the state. The system, if acquired, would probably be financed on the basis of an incremental increase in the laboratory screening fees charged for newborn screening. The literature indicates that tandem mass spectrometry "probably can be added to existing newborn screening systems for an incremental cost on the order of $10 per sample".[1]

*Potential Fiscal Impact:* If the Department chooses to adopt the new technology and expand the Newborn Screening Program to incorporate the additional testing, the Medicaid program and the state employee health benefit program will incur additional costs.

State-wide, the annual additional cost to all payers is estimated to be $1,260,000. (84,000 births x 1.5 rescreens x $10). Provisions included in P.L.91-1999 require the State and private insurers to cover the cost of the testing. In FY 1999, Medicaid paid for approximately 48,000 deliveries. The total annual cost to Medicaid is estimated to be $720,000. The state share of the total incremental cost would be about $275,000.

The additional testing protocol may also impact the cost of state employee health care benefits. Additional costs are estimated to be about $28,500. (1,900 births x 1.5 x $10). Estimated costs are subject to revision as more precise information is available from State Personnel and the Department of Health.

The inclusion of additional disorders in the newborn screening menu could increase the number of patients identified with metabolic disorders each year. If treatable conditions are identified early, the medical resources necessary to provide for ongoing nutritional and medical needs will increase. Reimbursement for the medical foods needed to treat these disorders must also be addressed because many third-party payers do not cover medical foods. The cost estimates above deal only with the cost of screening the general population; they do not include the additional expenses associated with the identification of affected individuals.

**Explanation of State Revenues:**

**Explanation of Local Expenditures:** As with the state, an expansion in the cost associated with the Newborn Screening Program may result in increased insurance premiums for the employee benefit plans purchased by local governments and school corporations. The impact on local units of government would vary depending on the specific benefit packages provided to employees.

**Explanation of Local Revenues:**

**State Agencies Affected:** All State Agencies; Department of Health, Newborn Screening and Children with Special Healthcare Needs; Family and Social Services Administration, Medicaid Division;

**Local Agencies Affected:**

**Information Sources:** Kathy Gifford, Assistant Secretary, Office of Medicaid Policy and Planning; Ed Blume, Newborn Screening Program, State Department of Health, 233-1252 and web page located at http://www.state.in.us/isdh/dataandstats/nat_intermpreg_marr/nat_1997/natality.htm; Keith Beesley, Department of Personnel, 232-3062; Ms. Jackie Bradford, Program advocate, 684-3557.

[1] "Tandem Smass Sectrometry in Newborn Screening" American College of Medical Genetics / American Society of Human Genetics Test and Technology Transfer Committee Working Group, Genetics in Medicine, July/August 2000, Vol. 2, No. 4; "Newborn Screening," Rhonda Gonzalez, NCSL Legisbrief, National Conference of State Legislatures, June/July 2000, Vol. 8, No. 27.